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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,047	10/20/2005	Tadao Saito	SPO-120	9241

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SALIWANCHIK LLOYD & SALIWANCHIK  
A PROFESSIONAL ASSOCIATION  
PO BOX 142950  
GAINESVILLE, FL 32614-2950

EXAMINER
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OLSON, ERIC

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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09/21/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/522,047	Applicant(s) SAITO ET AL.	
	Examiner Eric S. Olson	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **Detailed Action**

This application is a national stage application of PCT/JP03/09324, filed July 23, 2003, which claims priority to provisional applications JP2002-213305, filed July 23, 2002, and JP2003-50739, filed February 27, 2003. Claims 1-16 are pending in this application and examined on the merits herein. Applicant's preliminary amendment submitted January 19, 2007 is acknowledged wherein claims 10 and 13 are amended and new claims 15 and 16 are introduced, and the specification is amended to indicate continuity, along with Applicant's preliminary amendment submitted February 25, 2005, wherein claim 16 is amended.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a

disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl's 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a method for producing a phosphorylated dextran by carrying out a phosphorylation reaction in a formaldehyde solution.

The state of the prior art: While the prior art contains numerous instances of phosphorylating polysaccharides by reacting them with polyphosphoric acids, in various solvents including **formamide**,  $(\text{H}(\text{C}=\text{O})\text{NH}_2)$  the prior art does not indicate that **formaldehyde** ( $\text{H}_2\text{C}=\text{O}$ ) is useful for promoting this reaction. In the prior art, formaldehyde is known to react with polysaccharides by crosslinking or hydroxymethylating them, and heating dextran in formaldehyde solution would be expected to produce crosslinked or hydroxymethylated dextran, not phosphorylated dextran.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: In the absence of prior art guidance, the behavior of chemical species in reaction is unpredictable. One of ordinary skill in the art would not be able to predict what sort of effect formaldehyde

would have on a phosphorylation reaction. It is far from certain that the formaldehyde would actually promote the phosphorylation reaction.

The Breadth of the claims: The claimed invention encompasses any method of making a dextran phosphate involving simultaneously incubating the dextran with polyphosphate and formaldehyde.

The amount of direction or guidance presented: Applicant's specification briefly mentions phosphorylation reactions involving dextran, for example on p. 4, lines 33-34. However no details are given as to these reactions. By contrast, the specification describes detailed instructions for phosphorylation reactions using **formamide** as the solvent. It is also noted that none of the products produced are hydroxymethylated or crosslinked as would be expected if they were heated in the presence of formaldehyde.

The presence or absence of working examples: No working examples are provided for phosphorylation reactions taking place in a formaldehyde solution.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the development of novel reactions. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the claimed invention one of ordinary skill in the art would have to develop a novel reaction from scratch, using formaldehyde as a solvent or catalyst for phosphorylation reactions. This novel reaction is without precedent in the art or in Applicant's disclosure, and discovering, evaluating, and optimizing it would require unpredictable and undue experimentation.

*Genentech*, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the state of the art and the lack of guidance or working examples, Applicants fail to provide information sufficient to practice the claimed invention.

It is noted that the specification was translated from Japanese. It is suggested that the appearance of the word "formaldehyde" in the claims and specification is a typographical error and was intended to be "formamide".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (Reference included with PTO-892) Suzuki et al. discloses a study of the antitumor effects of Palmitoyl-dextran-phosphate (PDP), dextran phosphate, (DP) and palmitoyldextran (PD) which are known to enhance the antibody response of mice against implanted tumor cells. (p. 3448, left column, paragraphs 2-3) These dextran derivatives were administered to mice *in vivo* in 0.9% saline solution, which is

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reasonably considered to be a pharmaceutical composition, or for than matter a food composition because it could be orally ingested. (p. 3448, right column paragraph 3 – p. 3449, left column first paragraph) Administering the compound to a mouse comprises contacting the mouse's cells with the compound, and inherently carries out the method and effects of instant claims 7-10, 15, and 16. The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration. See *Ex parte Novitski* 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that the claiming of a new use, new function, or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3c. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it relates to the claimed invention herein.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (Reference included with PTO-1449, not the same as the Suzuki et al. reference cited above against claims 1-11 and 13-16) in view of Sacco

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et al. (Reference included with PTO-892) Suzuki et al. discloses a phosphorylated dextran and a method of making said dextran phosphate by reacting the dextran with polyphosphoric acid and triethylamine in anhydrous formamide. (p. 228, third paragraph) Suzuki et al. does not teach a heating step in the reaction, and does not teach a reaction carried out in formaldehyde solution.

Sacco et al. discloses a method of phosphorylating dextran comprising heating dextran in the presence of tributylamine and polyphosphoric acid. (p. 194, third paragraph)

It would have been obvious to one of ordinary skill in the art at the time of the invention to carry out the reaction of Suzuki et al. under heating, and to use a formaldehyde solution as the solvent. One of ordinary skill in the art would have recognized that Sacco et al. suggests adding heat to the phosphorylation reaction to speed up the rate of the reaction, since Sacco et al. describes a similar reaction, using a similar base and solvent, being carried out under heating. As regards the use of formaldehyde solution as the solvent, one of ordinary skill in the art would have been able to vary the solvent in the reaction with predictable results.

Thus the invention taken as a whole is *prima facie* obvious.

Claims 1-4, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent application JP52028583. (Reference included with PTO-1449, translation of abstract included with PTO-892, herein referred to as '583) '583 discloses a phosphorylated dextran palmitate and a method of making said dextran



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by heating dextran in a reaction mixture containing various reagents including polyphosphate. (abstract) '583 does not teach a reaction carried out in formaldehyde solution.

It would have been obvious to one of ordinary skill in the art at the time of the invention to carry out the reaction of '583 using a formaldehyde solution as the solvent. One of ordinary skill in the art would have recognized that various solvents can be used in the same reaction with predictable results. Therefore, one of ordinary skill in the art would have been able to evaluate various solvents in the reaction with predictable results.

Thus the invention taken as a whole is *prima facie* obvious.

### **Conclusion**

No claims are allowed i this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Olson



Patent Examiner

AU 1623

9/14/07

Anna Jiang



Supervisory Patent Examiner

AU 1623